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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,400	06/27/2003	Michael J. Pugia	2003P5601SUS (017191.042)	7945
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SIEMENS CORPORATION INTELLECTUAL PROPERTY DEPARTMENT 170 WOOD AVENUE SOUTH ISELIN, NJ 08830			GORDON, BRIAN R	
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			1797	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/608,400	<b>Applicant(s)</b> PUGIA ET AL.	
	<b>Examiner</b> Brian R. Gordon	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1-9-09.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-8,33,36 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-8,33, 36, and 40-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. The withdrawal of claim 39 is proper hereby maintained for the reasons recited in the previous action. The restriction requirement is hereby made Final.

5

### ***Response to Arguments***

2. Applicant's arguments filed May 1, 2009 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections  
10 are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As to applicant's comments regarding the possible thoughts Buecherl, such hypothetical thoughts are not pertinent to the issue. While applicant asserts the  
15 comments of Buecheler in reference to the incorporation of surface bound reagents ...on solid phase within the device is ambiguous, Hilliman and other references provide clear guidance as to how such elements are incorporated in such devices.

The sole issue is whether or not it would have been obvious at the time of the invention to modify the teachings/device of Buecheler to include a reagent absorbent  
20 substrate as claimed.

While applicant states that the substrate of the invention maybe located at various specific locations, the claim only requires that a single substrate be located adjacent (next, near, proximate, etc.) to the array of posts.

Applicant further discuss Applicant's problem. It should be noted that the motivation for combining references does not have to be the same motivation as that of applicant nor to solve the issues that applicant identify as problems.

There are numerours known reasons for employing reagent containing absorbent substrates, including mxing solutions, conducting reactions, or indicating the presence of a specific component in a sample or testing as taught by Hillman. Clearly Hillman provides sufficient motivation for the employment of an

As to the strength of capillary force in the passage or well, it is well known in the art as well as taught by Buechler that the capillary force can be controlled via the dimensions of the structure. Changing the size of a device is a design change that only involves routing skill in the art.

In view of the reasons given herein and those incorporated in the prior office actions, the previous rejections are hereby maintained.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3-8, 33, 36, and 40-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended claim 33 to recite the capillary force in the well is lower than capillary passageway. The examiner fails to locate support for the amendment.

It would appear that if this were the case, then device would not be enabled to function as intended by applicant. If a sample is transported through the microfluidic device via capillary force, then sample would not reach the well because the higher capillary force within the passageway would prevent the liquid sample from entering the well where the capillary force is lower.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 33 and 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how the device can function as claimed (as explained above in relevance to the capillary force).

As to claims 40-41, it is unclear what are the structural implications of "before" and "after". Claim 33 only requires that a vent (hole, opening) be located in the sidewall. There is no specific location given for the array posts relative to sidewall as such it is unclear what is meant by "before" and "after". Furthermore the terms are

relative. For example, two people traveling from opposite directions will each have different relative meanings of the terms.

***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can  
5 be found in a prior Office action.

8. Claims 3, 5, 6, 33, 36 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Pat. No. 6,113,855) in view of Hillman et al. (U.S. Pat. No. 4,756,884).

Regarding claims 5, 6, 33 and 36, Buechler teaches a microfluidic device  
10 structure comprising: an inlet port or entry 12; an enclosed capillary passageway 14 in fluid communication with the inlet port 12; an enclosed inlet chamber or well (e.g., distal region 16) having a substrate surface comprising an array of post structures (i.e., capillarity-inducing structures 30) that is also positioned adjacent the substrate; and a vent structure (i.e., escape port 18) (see col. 5, line 21 – col. 7, line 43; figures 1 & 4).

15 As shown in figure 1, the enclosed inlet chamber 16 is in fluid communication at one side or end side thereof with the enclosed capillary passageway 14. In addition, as shown in figure 1, the vent passageway 18 is positioned at a top side of the enclosed inlet chamber opposite the entry of the capillary passageway 14 into the enclosed inlet chamber 16. The device further comprises a lid 20 that further defines a top surface of  
20 well 16 (see figure 3).

Buechler does not specifically teach a reagent deposited on an adsorbent substrate, wherein the substrate is positioned adjacent to the uniform array of posts.

The Applicant is advised that the Supreme Court recently clarified that a claim can be proved obvious merely by showing that the combination of known elements was obvious to try. In this regard, the Supreme Court explained that, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp.” An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. Furthermore, the simple substitution of one known element for another is likely to be obvious when predictable results are achieved. See *KSR Int’l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007) (see MPEP § 2143).

In that regard, Buechler does teach the incorporation of surface bound reagents, e.g., antibodies, on a solid phase within region 16 containing the assay volume and adjacent capillarity-inducing structures 30 (see, e.g., col. 4, lines 42 – 67; col. 5, lines 36 – 67; figures 1 – 4).

The use of reagent-containing absorbent substrates with similar testing devices is well known in the art. For example, Hillman et al. teaches a similar testing device that uses capillary flow and surface bound or coated reagents. Hillman also teaches that the reagents can be provided on an absorbent substrate comprising a sponge, gel,

membrane or filter paper within the reaction unit of the disclosed device (see, e.g., col. 15, line 66 – col. 17, line 30; in particular, col. 16, lines 55 – 61). Consequently, as shown by Hillman, a person of ordinary skill in the art would have recognized the predictable use of reagent-containing absorbent substrates with similar testing devices using capillary flow in facilitating sample fluid flow control and assaying. Therefore, it would have been obvious to a person of ordinary skill in the art to substitute and incorporate a reagent-containing absorbent substrate with the disclosed microfluidic device in order to facilitate effective sample fluid flow control and subsequent testing.

Regarding claim 3, Buechler teaches the incorporation of an array of posts comprising more than one row or column of posts 30 (see figures 3, 4, 5B and 6B).

Regarding claims 5 and 6, these claim limitations would have been obvious to a person of ordinary skill in the art upon incorporation of the reagent-containing absorbent substrate with the device structure taught by Buechler. With respect to claim 5, the array of posts could be positioned above or before the absorbent substrate within well 16 so that a uniform flow of sample fluid would be established before contacting the reagent-containing absorbent substrate for analysis. With respect to claim 6, upon incorporation of the absorbent substrate, it would have been obvious to a person of ordinary skill in the art to incorporate the absorbent substrate to contact the array of posts so that a uniform distribution of sample fluid would result in contacting the reagent-containing absorbent substrate.

Regarding claim 36, upon incorporation of the absorbent substrate, it would have been obvious to a person of ordinary skill in the art that the array of posts 30 could be



positioned between entry 12 and the absorbent substrate so that a uniform flow of sample fluid would contact the reagent-containing absorbent substrate.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler and Hillman et al., and further in view of Peters (U.S. Pat. No. 6,296,126).

5           Regarding claim 4, Buechler is silent to the specific teaching of incorporating wedge-shaped cut-out structures with the disclosed microfluidic device.

          However, as shown in figure 3b, Peters does teach the incorporation of wedge-shaped cut-out structures (post or columnar projection 9 having wedge-shaped cut-outs 1) within a microfluidic apparatus for facilitating effective fluid control within a  
10 microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4).

          The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007) (see MPEP § 2143).

          Therefore, as evidenced by Peters, a person of ordinary skill in the art would  
15 have recognized the suitability and predictable incorporation and use of wedge-shaped cut-out structures within a microfluidic apparatus for the intended purpose of facilitating effective fluid control (see also MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these wedge-shaped cut-out structures within the disclosed  
20 microfluidic apparatus for facilitating effective fluid control (see MPEP § 2143.02).

          Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of wedge-shaped cut-out structures as claimed with the disclosed

microfluidic device in order to provide an effective for effective sample fluid control within the microfluidic apparatus.

10. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler and Hillman, and further in view of Columbus (U.S. Pat. No. 4,233,029).

5           Regarding claim 7, as shown in figure 7a, Columbus further teaches the incorporation of ramp structures comprising a plateau surface structure configuration (e.g., truncated ridges 46) within a similar testing the device (see, e.g., col. 8, lines 1 – 51).

          The combination of familiar elements is likely to be obvious when it does no more  
10   than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007) (see MPEP § 2143).

          Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a weir structure as claimed for facilitating effective sample fluid flow with the disclosed microfluidic device.

15           Regarding claim 8, Beuchler does not specifically teach the incorporation of at least one groove structure extending across the inlet chamber 16.

          Columbus teaches the use of groove structures (e.g., 42 & 44) for facilitating uniform fluid flow within microfluidic devices (see, e.g., col. 5, lines 1 – 55; figure 3).

          The combination of familiar elements is likely to be obvious when it does no more  
20   than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007) (see MPEP § 2143).

Hence, as shown by Columbus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a groove structure with an analytical microfluidic device for facilitating uniform sample fluid introduction into the device for processing and analysis. Therefore, it would have been  
5 obvious to a person of ordinary skill in the art to incorporate a groove structure as claimed with the disclosed microfluidic device in order to facilitate effective uniform sample fluid distribution within the device.

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in  
10 this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within  
15 TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later  
20 than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

10 Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

15 system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/  
Primary Examiner  
Art Unit 1797